

EXHIBIT 9

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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

**IN RE: DA VINCI SURGICAL ROBOT
ANTITRUST LITIGATION**

Lead Case No. 3:21-CV-03825-VC

**THIS DOCUMENT RELATES TO:
ALL ACTIONS**

**PLAINTIFFS' OPPOSITION TO
INTUITIVE'S CROSS-MOTION FOR
SUMMARY JUDGMENT AND
REPLY IN SUPPORT OF PARTIAL
SUMMARY JUDGMENT**

The Hon. Vince Chhabria

Date: June 8, 2023
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I. Introduction & Statement of Issues

Intuitive is incorrect that this case turns on a “legal issue” involving “FDA clearance.” Mot. at 1.¹ This federal antitrust case challenges various methods Intuitive has used to block Plaintiffs from hiring independent repair companies (“IRCs”) to repair the instruments (“EndoWrists”) used with Intuitive’s da Vinci surgical robots (“da Vincis”) or service the robots themselves. As such, this case presents material factual inquiries—including whether a) Intuitive had monopoly power in the markets for minimally invasive soft-tissue surgical robots (“Robots”) and EndoWrists, b) Intuitive tied the sale of da Vincis to its prohibitions on EndoWrist repair and da Vinci servicing, c) Intuitive’s restraints on trade inflicted antitrust injury on Plaintiffs, and d) Intuitive’s exclusionary conduct is justified by a procompetitive rationale.

None of these inquiries requires interpretation of FDA regulations. Intuitive’s central defense—that premarket clearance inhibits EndoWrist repair by IRCs regardless of the lawlessness of Intuitive’s conduct—turns on the factual question of whether FDA would take action to stop IRCs from repairing EndoWrists and extending their useful lives. Since IRCs performed precisely this kind of EndoWrist repair for nearly 18 months without any enforcement action—or even a formal warning letter—from the agency, we already know the answer. And we know why: because “FDA,” in the words of Intuitive’s senior director of regulatory affairs, “does not require nor limit the number of uses for [EndoWrists] instruments.” The record is unambiguous on this score, and Plaintiffs, not Intuitive, are entitled to partial summary judgment on this issue as a result. The same goes for Intuitive’s power in the separate markets for EndoWrists and Robots. And Intuitive’s brazen request for summary judgment on its pretextual “procompetitive rationale” should be denied.

II. Factual Background

Intuitive’s summary judgment motion makes much of its purported “exhaustive testing programs,” arguing that “use limits would be needed for EndoWrists” to ensure “a reasonable

¹ “Mot.” refers to the Opposition of Defendant Intuitive Surgical, Inc. to Plaintiffs’ Motion for Summary Judgment and Cross-motion for Summary Judgment (Dkt. 153).

margin of safety.” Mot. at 4. In support, Intuitive accompanied its motion with a declaration dated April 12, 2023, months after the close of fact discovery, that attempts to put a new spin on the extensive record developed over several years here and in the two now-settled Florida cases. *See* Dkt. 153-2 (Rosa Dec.). This belated declaration is inconsistent with the record developed in fact discovery, which tells a very different story.

Contrary to its oft repeated characterization of its testing as “exhaustive,” Intuitive rarely tested EndoWrists to failure, instead focusing on tests intended only to demonstrate reasonable—although notably imperfect—reliability for an arbitrary preset number of lives (usually 10). Corrigan Dec.² Ex. 14 at 35:5–36:23, 46:24–47:20; *id.* Ex. 31 at -955. And even that testing regularly demonstrated that EndoWrists are reliable well beyond its arbitrary use limits. *See* Spector Dec. Ex. 98 at -172 (2002 testing results showing the “average number of uses supported . . . was 26”); *see also* Corrigan Dec. Ex. 47 at -188; Spector Dec. Ex. 99.

Tellingly, Intuitive anticipates EndoWrists can and will fail, even within those preset use limits. One engineer, charged with overseeing testing of Xi EndoWrists, explained that in order to “launch” the “instruments need to be 85 percent reliable,” meaning that Intuitive “expect[s] the remaining 15 percent to like fall out during use.” *Id.* Ex. 100 at 69:16–70:1. When FDA noted that Intuitive “appear[ed] to have set arbitrary performance goals for reliability at confidence of either 85% at 85% or 90% at 90%” for EndoWrists, *id.* Ex. 101 at -004, Intuitive explained that it felt comfortable with such high failure rates because surgeons can readily identify and remediate in real time the kinds of failures EndoWrists experience, *see id.* Ex. 102 at -740 (explaining that Intuitive’s “approach for establishing performance goals for reliability and confidence . . . is based on the clinical and/or usability risk that the device poses to the patient and/or user”). That is, Intuitive’s approach to patient safety is to rely on surgeons to ensure that the inevitable failures do not harm patients, rather than to eliminate EndoWrist failures.

In fact, one surgeon testified that he had an “EndoWrist fail during surgery . . . 50 times or

² “Corrigan Dec.” refers to the Declaration of Jeffrey J. Corrigan in Support of Plaintiffs’ Corrected Motion for Partial Summary Judgment (Dkt. 149-1).

so,” all before the use limit expired. *Id.* Ex. 103 at 69:1–70:1. Intuitive’s own expert acknowledged that an EndoWrist malfunctions “every few months.” *Id.* Ex. 104 at 94:2–14. But as Dr. Estape testified, when an EndoWrist fails during surgery, the fix is simple: “I just tell them to change out the instrument.” *Id.* Ex. 103 at 69:12–14; 73:9–19 (“[I]t’s a simple procedure. You just get me another instrument so I can continue with the procedure.”). Another surgeon similarly testified that, when an “EndoWrist instrument is not functioning properly[,] . . . We take it out and put another one in. That’s what we’ve done every time.” *Id.* Ex. 105 at 16:24–17:17. Intuitive’s executive VP explained that if an EndoWrist is not functioning properly, “what I would hope [surgeons] do is they pull it out, put in another, and continue the operation . . . expeditiously for the patient.” *Id.* Ex. 106 at 55:1–10. These failures are hardly “catastrophic.” Mot. at 4. Indeed, none of the 50-plus incidents of mid-surgery failure referenced above resulted in anything close to a catastrophic injury. Spector Dec. Ex. 103 at 69:15–20; *see also id.* Ex. 107 at 84:1–24. The reality is that EndoWrists can and do fail before reaching their use limits. And Intuitive’s RMA data indicate that such failures are no more likely to occur on a “later” use than on an “earlier” one. *See id.* Ex. 108 at -617–618; *see also id.* Ex. 109 at 74:12–16 (“An RMA is an instrument or a device that’s been returned from the field.”).³

The record, in short, does not support Intuitive’s claim that its preset use limits prevent EndoWrist failures. Instead, the evidence indicates those use limits serve to facilitate Intuitive’s business model—i.e., to “derive its revenues from high margin disposable instruments, as well as high margin ‘resposable’ instruments which can be resterilized and reused only for the number of times allowed by the company.” Corrigan Dec. Ex. 9 at -675; *see also id.* at -682 (“The number of reuses will be controlled to reflect . . . the gross margin and price desired.”). Intuitive forces customers to agree to contractual prohibitions on any repair or modification of EndoWrists or the use of EndoWrists beyond their arbitrary use limits, *id.* Ex. 12 at -540-542; *id.* Ex. 13 ¶¶ 4, 107, and embeds a use-counter memory chip in each EndoWrist that renders it useless once the use limit is

³ Indeed, when asked why Intuitive did not set usage limits “even lower to eliminate” failures, Intuitive executive David Rosa testified, “I don’t know if there is a really strong correlation” between uses and failure rates. Spector Dec. Ex. 111 at 94:3-14.

reached, regardless of the instrument's condition, *see* Spector Dec. Ex. 110 at 130:19–131:6; *see also* Corrigan Dec. Ex. 66 at -294.

IRCs like Restore and Rebotix threatened this business model by offering hospitals the ability to bypass the arbitrary use counter, tune-up the EndoWrists they owned, and use them to the full extent of their useful lives. *See id.* Ex. 18 at -692–695 (noting Rebotix began work on a process to repair EndoWrists and reset its use counter in 2012, entered the international market in 2016, and began doing business in the U.S. in 2018); *id.* Ex. 22 at -016 (Intuitive detected usage of repaired EndoWrists in the U.S. by no later than May 2018).⁴ Intuitive responded to the risk of actual competition by threatening to void the warranty on da Vincis used with repaired EndoWrists, and suggesting (incorrectly) that FDA regulations prohibit EndoWrist repair. *See, e.g., id.* Ex. 29; *id.* Ex. 30. Recognizing that Restore's and Rebotix's repair activities were focused on the earlier (Si) generation of EndoWrists, *see* Spector Dec. Ex. 112, Intuitive began phasing out that generation of robots, *see id.* Ex. 113 at 212:25–213:4, even though “the Si ha[d] been [Intuitive's] most popular product and it remain[ed] in heavy use.” *Id.* Ex. 114 at -250. In its place, Intuitive offered a newer (X/Xi) generation of robots whose EndoWrists include an “encrypted” chip meant “to prevent people from reprocessing our instruments.” *Id.* Ex. 115. Intuitive also investigated its own refurbishment program—intended to “displace” IRCs repairing EndoWrists, *id.* Ex. 110 at 254:19–24—and extended the use limits on its highest volume EndoWrists. Corrigan Dec. Ex. 42; Spector Dec. Ex. 100 at 108:14–109:10. Tellingly, increasing the use limits on those instruments (which Intuitive now insists are critical safety features) “d[id] not involve any changes to the intended use(s) or instrument design.” Corrigan Dec. Ex. 44 at -700; *see also id.* Ex. 45 at 22:6–23.

⁴ Intuitive's description of Rebotix's process for bypassing the use counter is highly misleading. *See* Spector Dec. Ex. 116 ¶¶ 79–97 (describing Rebotix's process, in detail, based on visit to Rebotix repair facility and observation of “several complete EndoWrist repair processes”). Rebotix has received multiple third-party quality and safety certifications for that process. *See id.* Ex. 114 at -294–295. And when financial analysts investigated the potential impact of this technology on Intuitive's profitability, they observed that “all experts agreed that any regulation action/enforcement is highly unlikely given FDA's clear comfort around the safety of refurbished devices broadly and the fact that there has been no signal of incremental patient risk to date with repaired da Vinci instruments.” Corrigan Dec. Ex. 78 at -057.

FDA, for its part, has *never* taken the position that use limits are required under federal law. Intuitive’s senior director of regulatory affairs made this crystal clear when asked to respond to a hospital’s request for “documentation of the latest FDA certifications for Xi and Si robots and proving the FDA granted the 510K based on a required limitation of the number of uses per EndoWrist Instrument.” *Id.* Ex. 33 at -242. “We can certainly provide the latest FDA 510(k) Clearance letters,” he explained, “[b]ut this will not provide the information requested.” *Id.* at -241. “Just so you know, FDA does not require nor limit the number of uses for our EW instruments. During the 510(k) submission process, we provide data to FDA that supports the stated number of lives for a particular instrument that we state in our labeling.” *Id.* Consistent with that understanding, FDA has never sent a formal warning letter to, much less initiated an enforcement action against, any IRC for resetting an EndoWrist’s use counter without seeking 510(k) clearance—nor has FDA issued any binding rule, guidance document, or policy statement to that effect—even though it has been aware of this practice “[f]or the better part of a decade.” Mot. at 15.

III. Intuitive is not entitled to summary judgment on any of Plaintiffs’ claims.

Intuitive is not entitled to summary judgment on either Plaintiffs’ EndoWrist-related claims or their service-related claims.

A. Intuitive is not entitled to summary judgment on Plaintiffs’ EndoWrist claims.

1. Intuitive’s arguments against Plaintiffs’ showing of antitrust injury fail.

Intuitive’s first argument takes aim at the existence of a cognizable antitrust injury. Mot. at 13. “In order to find that an antitrust injury exists, [courts] must examine both the nature of the injury and whether the injury is causally related to the antitrust violation.” *Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1003 (9th Cir. 2008) (citing *Datagate, Inc. v. Hewlett-Packard Co.*, 941 F.2d 864, 867 (9th Cir. 1991)). Intuitive does not contest that the injuries identified by Plaintiffs—including being forced to overpay for new EndoWrists from Intuitive and having to buy them more frequently because of artificially suppressed use limits—are, if proven, an “injury of the type the antitrust laws were intended to prevent.” *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). Intuitive offers three arguments, however, questioning whether this injury

“flows from that which makes defendants’ acts unlawful.” *Glen Holly Ent., Inc. v. Tektronix, Inc.*, 352 F.3d 367, 371 (9th Cir. 2003) (quoting *Brunswick*, 429 U.S. at 489); *see* Mot. at 13–20. None withstands scrutiny.

a. FDA regulation does not preclude Plaintiffs’ antitrust injury.

Intuitive’s primary attack on Plaintiffs’ EndoWrist-related claims is to recast a factual question—whether and how competitive entry would have occurred in the but-for world—as a legal argument “that the governing regulatory scheme” (specifically, 510(k) clearance) “precluded” IRCs from repairing EndoWrists, including by resetting the instruments’ use counter to extend their useful lives beyond Intuitive’s preset use limits. Mot. at 1, 13. While that gambit might have some chance of success in a *competitor* case (although both Florida courts rejected it⁵), where a finding that the specific competitor behaved unlawfully in the actual world could foreclose its recovery, it fails in this *customer* case. To succeed here, Intuitive would need to show not only (1) that the IRCs’ business was unlawful (it wasn’t) but also (2) that FDA would have sought and won an injunction halting that business (even though it did no such thing, nor even took steps in that direction, in the actual world); and (3) that no IRC(s) would have obtained 510(k) clearance were it actually required (even though Iconocare already has done so in the actual world). These second and third requirements plainly present disputed questions of material fact.

To show antitrust injury, Plaintiffs must offer evidence “that diminished consumer choices and increased prices are the result of a less competitive market due to either artificial restraints or predatory and exclusionary conduct.” *FTC v. Qualcomm Inc.*, 969 F.3d 974, 990 (9th Cir. 2020). “It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury.” *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 114 n.9 (1969). And whether Plaintiffs’ injury “flows from” Intuitive’s conduct presents “an intensely factual question” that turns on

⁵ *See Restore Robotics, LLC v. Intuitive Surgical, Inc.*, 2022 WL 1495005, at *3–4 (N.D. Fla. Apr. 11, 2022); *Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, 2022 WL 3272538, at *5–7 (M.D. Fla. Aug. 10, 2022).

“common law principles of causation.” *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 872 (N.D. Cal. 2021) (quoting *Pac. Shores Props., LLC v. City of Newport Beach*, 730 F.3d 1142, 1168–69 (9th Cir. 2013)). Here, one core factual question is whether “entry would actually have occurred” and “would have lowered prices or encouraged innovation . . . but for the [tying] arrangement.” H. Hovenkamp & P. Areeda, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 1769 (4th & 5th Eds. 2018–2022).

The 510(k) regulatory scheme impacts Plaintiffs’ showing of antitrust injury only if (and only to the extent that) it would have deterred IRCs from offering EndoWrist repair even in the but-for world absent Intuitive’s ties and threats. But even if required, 510(k) clearance represents, at most, a modest hurdle—one that has already been cleared by one IRC (for what Intuitive considers its “highest risk instrument,” no less), *see* Corrigan Dec. Ex. 83; Spector Dec. Ex. 110 at 178:2-7, and one that would have been cleared more widely had FDA required it and Intuitive allowed hospitals to use IRCs. Corrigan Dec. Ex. 1 ¶¶ 287-88. This reality contrasts sharply with Intuitive’s cited cases (Mot. at 13–14 & n.5), in which competitive entry “was effectively blocked” by some law or regulation. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017). Intuitive’s regulatory argument thus would not warrant summary judgment *even if* Intuitive’s misguided understanding of how FDA has applied and would apply the 510(k) requirement were correct.

The argument separately fails for the more basic reason that *FDA has not required* 510(k) clearance for EndoWrist repair.⁶ Intuitive’s senior director of regulatory affairs conceded as much: “FDA does not require nor limit the number of uses for our [EndoWrist] instruments,” and, as a result, “FDA 510(k) clearance letters” do not “prov[e] the FDA granted the 510K based on a required limitation of the number of uses per Endo-Wrist Instrument.” Corrigan Dec. Ex. 33 at -241–

⁶ In this regard, Intuitive repeatedly and inaccurately asserts that FDA “cleared the instruments as ‘limited use’ devices.” Mot. at 5, 6, 23, 24. But there is no such thing under the applicable regulations. Corrigan Dec. Ex. 84 ¶¶ 62–69. There are two relevant categories of “durable” medical devices: (1) single-use and (2) reusable medical devices, and FDA has cleared EndoWrist as “reusable” devices. *Id.* ¶¶ 63-65. They remain “reusable” following repair.

242; *see also* Spector Dec. Ex. 117 at 141:13-18, 142:19–22. And Intuitive cannot point to a single instance in which FDA issued a rule, guidance document, or any other *decision binding on the agency* requiring 510(k) clearance for EndoWrist repair. Nor can Intuitive identify *any* statement by *any* agency official, with authority to bind the agency, that definitively states that 510(k) clearance is required. The record evidence on which Intuitive relies primarily involves correspondence in which Rebotix and FDA staffers go back and forth as to 510(k) clearance requirements. *See* Mot. at 15. But when Rebotix ultimately asked to appeal any decision that its activities required 510(k) clearance, FDA responded that no such decision had ever been made. In a July 2022 email, an FDA reviewer acknowledged that, “[i]n my prior communications,” he “used the term ‘decision’ in a manner that may have incorrectly implied that FDA had made an official regulatory determination related to Rebotix.” Corrigan Dec. Ex. 85 at -839. That reviewer then “clarif[ied]” that the parties’ prior correspondence—of the exact sort on which Intuitive now rests its argument—did not represent FDA’s *official* position or bind the agency in any way:

To clarify, FDA conducted a preliminary **informal assessment** of the limited materials previously provided by Rebotix, and FDA has not conducted an official regulatory evaluation. Informal communications with FDA staff do not represent the formal position of FDA and do not bind or otherwise obligate or commit the agency to the views expressed. . . . [T]here is nothing for Rebotix to appeal at this time.

Id. (second emphasis added).⁷ This email came *after* the letter that, according to Intuitive (Mot. at 15), represents an “official” FDA statement—a statement that, at any rate, said only that Rebotix “*may be remanufacturing*” EndoWrists “in a manner that *potentially* violates the FD&C Act.” Spector Dec. Ex. 118 at -417 (emphasis added). The record, accordingly, leaves no doubt that, at least as of July 2022, FDA had made no determination that Rebotix’s activities—including the use of its Interceptor—required 510(k) clearance. Thus, Intuitive is simply incorrect in asserting that “[f]or the better part of a decade – ever since the issue first arose – FDA has consistently made clear that

⁷ Intuitive argues that this email represents nothing more than the agency’s “determination” that its prior statements did not represent a “final *appealable* order.” Mot. at 15. Whatever Intuitive means by this, the fact remains that FDA has not required—in an “appealable” fashion or otherwise—510(k) clearance for IRCs performing EndoWrist repair.

modifications of EndoWrists to reset their use counters is remanufacturing that requires 510(k) clearance.” Mot. at 15.⁸

The reality is that FDA, understanding that imposing further regulatory requirements on IRCs performing medical device repair “would substantially increase the cost to hospitals (and, ultimately, to patients) of using reusable devices,” Corrigan Dec. Ex. 84 ¶ 23, has adopted a cautious approach. FDA has publicly acknowledged that, in the context of medical device repair, there is ongoing ambiguity as to “whether an activity is servicing”—in which case 510(k) clearance is not required—“or remanufacturing,” in which case 510(k) clearance may be required. *Id.* Ex. 89 at 1.⁹ According to Plaintiffs’ FDA expert, FDA has not yet acted because “[the agency] does not see the public health case for subjecting [IRCs] to heightened regulatory requirements, making the inevitable increase in healthcare costs of doing so unjustifiable.” *Id.* Ex. 84 ¶ 24; *see also id.* Ex. 86 at 275:16–20 (“[T]hey [FDA] very overtly said, we do not find compelling evidence that says that there is any public health harm in the activities [and] therefore has made the decision that right now the economic burden of making” those activities subject to heightened regulatory requirements was

⁸ That Iconocare determined that its business model would benefit from 510(k) clearance—presumably by undermining efforts by Intuitive to discourage its customer base by raising regulatory concerns—does nothing to change this reality. Corrigan Dec. Ex. 84 ¶¶ 29–34. Iconocare, unlike others, intended to resell repaired EndoWrists to other hospitals, meaning Iconocare indisputably intended to “introduc[e]” those devices “into interstate commerce for commercial distribution,” one of the two independent requirements for 510(k) clearance. 21 C.F.R. § 807.81(a); *see* Corrigan Dec. Ex. 84 ¶¶ 57–61.

⁹ Although Intuitive frequently assumes that an entity that is a “remanufacturer” must, for that reason alone, seek 510(k) clearance, the remanufactured device must also be “introduc[ed] into interstate commerce for commercial distribution,” 21 C.F.R. § 807.81(a), for clearance to be required. And FDA has never declared that an IRC that never takes ownership of or resells a repaired device satisfies this requirement. *See* Corrigan Dec. Ex. 84 ¶¶ 57–61. Intuitive, as it did in seeking to exclude Plaintiffs’ FDA expert’s opinion, maintains that the Ninth Circuit has resolved in its favor the interpretative question raised by this requirement. *See* Mot. at 17 (citing *U.S. v. Kaplan*, 836 F.3d 1199 (9th Cir. 2016)). But, as Plaintiffs have previously explained, *see* Dkt. 161 (Opp. to Trautman *Daubert* Mot.) at 11–12, that is wrong—principally because *Kaplan*’s holding that “a physician’s use of a consumable, single-use device on a paying patient satisfies the ‘held for sale’ element under 21 U.S.C. § 331(k),” 836 F.3d at 1211, is hardly dispositive of the question here: how FDA has understood the phrase “held or offered for sale,” 21 C.F.R. § 807.3(b), for purposes of reusable medical device repair.

unjustifiable).¹⁰ The record supports her. Indeed, a Rebotix executive testified that the FDA reviewer’s email that “FDA has not conducted an official regulatory evaluation,” *Id.* Ex. 85 at -839, followed a meeting that “included some fairly high people in the FDA” in which “it was clear that the walk back was occurring and that only an informal assessment was made.” Spector Dec. Ex. 119 at 99:5–100:3.

Manufacturers have unsuccessfully lobbied FDA for decades for a version of the ruling Intuitive now asks of this Court in this private antitrust lawsuit. Corrigan Dec. Ex. 84 ¶¶ 23, 73. Notably, FDA previously revoked guidance that required “reconditioners” and “rebuilders” to seek 510(k) clearance and indicated further rulemaking was required “to consider identifying the used device market, for regulatory purposes, in terms of ‘refurbishers,’ ‘as-is remarketers,’ and ‘servicers’ whose activities do not significantly change the safety, performance, or use of a device.” 63 Fed. Reg. 67076-01 (Dec. 4, 1998). But FDA has yet to finalize any such guidance or rulemaking, Corrigan Dec. Ex. 84 ¶¶ 7, 15, and the Court should reject Intuitive’s invitation to ignore FDA’s caution in this area and require 510(k) clearance under circumstances where FDA has not.¹¹

The relevant question here is whether and how IRCs would have entered the EndoWrist repair and replacement market in the but-for world. The record is unambiguous that, absent at least a

¹⁰ EndoWrists fail within Intuitive’s use limits, *see, e.g.*, Spector Dec. Ex. 120 at 99:10-101:19; *id.* Ex. 116 ¶¶ 235–49, 279–88, and there is no evidence of any increased risk of failure caused by refurbished EndoWrists. *See, e.g.*, Dkt. 149 (Pls.’ SJ Br.) at 7; *see also* Spector Dec. Ex. 116 ¶¶ 157–173. And, as noted *supra*, when instrument failures occur, they are routinely resolved by surgeons simply replacing the instruments. *Id.* Ex. 103 at 69:1-73:19; *id.* Ex. 121 at 43:20-44:19; *see also* Corrigan Dec. Ex. 7 ¶¶ 26–27; Spector Dec. Ex. 122 at 46:22-47:1.

¹¹ This Court has recognized, in the Lanham Act context, that “[c]ourts regularly evaluate the lawfulness of a party’s behavior under federal regulations.” *Surgical Instrument Serv. Co., Inc. v. Intuitive Surgical, Inc.*, 571 F. Supp. 3d 1133, 1143 n.8 (N.D. Cal. 2021) (“*SIS*”). But even there the Ninth Circuit has urged caution where to permit the plaintiff “to proceed with a claim that Defendants violated this law when the FDA did not so determine would, in effect, permit [plaintiff] to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make.” *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1049 (9th Cir. 2022) (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 930 (9th Cir. 2010)). Those same principles of restraint apply with at least equal force here, where the relevant question turns on FDA’s actual enforcement decisions (rather than pure regulatory interpretation). Indeed, any determination that the FDA *should have* enforced the 510(k) requirement against IRCs’ EndoWrist repairs would not change the reality that FDA has yet to do so.

clear and binding FDA statement to the contrary, competitive entry would not be constrained by 510(k) regulations. Indeed, multiple IRCs performed EndoWrist repair without 510(k) clearance in the real world—before being driven from the market by Intuitive’s ties and threats—and FDA never initiated an enforcement action against any of them, *see id.* Ex. 22 at -016; *id.* Ex. 65 at 132:17-24, even though FDA has been aware of (and communicated with IRCs about) this issue “[f]or the better part of a decade.” Mot. at 15. Moreover, Intuitive itself marketed and sold EndoWrists beyond the use limits indicated in those instruments’ 510(k) application *for nearly a decade* without seeking further 510(k) clearance. *See* Spector Dec. Ex. 123 at -654; *see also, e.g.*, Corrigan Dec. Ex. 90 at -718. Even when Intuitive (after the filing of this lawsuit) reversed course and decided to seek 510(k) clearance, and even after being told by an FDA staffer that it should “roll back” the number of uses on those instruments while the agency considered that application, Intuitive continued to market those instruments at their not-yet-cleared use limits. *Id.* Ex. 45 at 35; *id.* Ex. 94 at 29–30. Intuitive concedes that FDA “*disagreed* with this judgment,” Mot. at 18, but its regulatory officials insist that its conduct has always been lawful and reasonable. *See* Corrigan Dec. Ex. 94 at 36–41; Spector Dec. Ex. 111 at 124:5–130:7.

Intuitive’s decision to continue marketing the EndoWrists at issue even in the face of direction from FDA staff not to do so underscores the reality that mere pushback from FDA staff does not compel firms to withdraw or withhold their products from the market. Indeed, Intuitive’s own FDA expert acknowledged that companies often continue to market medical devices that are the subject of enforcement action while those actions are litigated in federal court. *See* Corrigan Dec. Ex. 87 at 17:11–18:14; Spector Dec. Ex. 124 ¶ 6. And when Intuitive considered its own refurbishment program, it determined that 510(k) clearance was not required to reset the lives of EndoWrists. *See* Corrigan Dec. Ex. 91 at -573–574. It should come as no surprise, then, that a Deutsche Bank analyst who spent “several months” on “due diligence” concluded that “FDA’s comfort around this practice regarding patient safety is quite clear.” *Id.* Ex. 77 at -993; Spector Dec. Ex. 125 at 82:17–85:11. In fact, “a majority of regulatory experts” Deutsche Bank spoke with “came to the conclusion that Restore Robotics is not in violation of FDA rules as a third-party service

provider of refurbished instruments.” Corrigan Dec. Ex. 78 at -055.

Intuitive makes one last-ditch attempt to find an FDA shield from competition: it now states, for the first time in the four years it has been litigating this issue, *in a statement issued in March of this year*, that so long as an IRC has 510(k) clearance to perform EndoWrist repair, Intuitive will not enforce its contractual prohibitions on such repair. *See* Mot. at 15. But Intuitive can point to no prior announcement or record evidence to support that late-arriving argument, and its contracts make no such distinction, prohibiting *all* third-party repair regardless of regulatory status. Corrigan Dec. Ex. 12 at -540-542; *id.* Ex. 13 ¶¶ 4, 107; *see also* Spector Dec. Ex. 126 at 36:23–37:2 (testifying that Franciscan did not pursue talks with Rebotix because “language in our contracts with Intuitive [] prevented us from taking any further action”); *id.* Ex. 127 at -648. And cease-and-desist letters sent by Intuitive did not allow for this possibility. *E.g.*, *id.* Ex. 128; *id.* Ex. 129. Two intervening events offer an alternative explanation for Intuitive’s brand new position. First, Iconocare has now secured 510(k) clearance, *see* Corrigan Dec. Ex. 83, meaning that even if 510(k) clearance were required, there would be at least some competition in the but-for world. Second, in settlements with Intuitive, both Restore and Rebotix extracted concessions that, if they secured 510(k) clearance, Intuitive would not object to their performing EndoWrist repair. *See* Spector Dec. Ex. 130; *id.* Ex. 131. The obvious implication is that external events have forced Intuitive’s hand, and this Court should not credit Intuitive’s effort to argue retroactively that, had IRCs possessed 510(k) clearance, Intuitive would not have hindered those IRCs from entering the market.¹²

The undisputed record is that IRCs could (and did) enter the EndoWrist repair market without 510(k) clearance—and that Intuitive (not FDA) forced them out of that market. As such, that regulatory scheme has no bearing on Plaintiffs’ showing of antitrust injury and the Court should grant Plaintiffs’ motion for partial summary judgment on this point. *See* Dkt. 149 (Pls.’ SJ Br.).

¹² Otherwise, it is hard to reconcile Intuitive’s newfound comfort with resetting Si instruments (for which Iconocare has 510(k) clearance) with its assertion that “life extensions were made possible by years of improvements in the more advanced X/Xi instruments that were not applicable to the older S/Si instruments, which remain prone to earlier failure.” Mot. at 18.

b. Intuitive’s argument that Plaintiffs have not expressed interest in EndoWrist repair is incorrect and irrelevant.

Intuitive argues that Plaintiffs cannot establish antitrust injury because they “would not have used non-cleared instruments in the face of FDA’s unqualified position on that question.” Mot. at 18. First, there is no dispute that each Plaintiff purchased EndoWrists, and the evidence (including the opinions of Plaintiffs’ economic expert) indicates that, absent Intuitive’s exclusionary restraints, Intuitive would have lowered EndoWrist prices and/or increased their artificially suppressed use limits for *all* customers to meet IRC competition. *See* Corrigan Dec. Ex. 1 § VI.A-C.¹³ The evidentiary support for this market-wide impact theory—which does not require that Plaintiffs themselves would have purchased repaired EndoWrists in the but-for world—makes immaterial whether any given Plaintiff expressed interest in contracting with IRCs. Indeed, none of Intuitive’s cases involve consumers who indisputably participated in the affected market. Mot. at 19

Second, because FDA has never taken the “unqualified position” that 510(k) clearance is required for IRC repair of EndoWrists, *id.* at 18, it is of no moment that witnesses from Franciscan or Valley Medical indicated that, had the agency done so, they would require evidence of that clearance prior to working with an IRC. *See, e.g.,* Spector Dec. Ex. 132 at 37:18-19 (“[I]f the FDA **requires** a device to be cleared, . . . we would purchase a cleared device.” (emphasis added)). Some of Intuitive’s cited testimony is even more misleading. For example, Intuitive cites a Franciscan employee acknowledging that “if a device is *single use* but has been remanufactured to be reused and the single use device required FDA clearance,” Franciscan “would not purchase a device that wasn’t FDA cleared.” *Id.* Ex. 133 at 51:24–52:8 (emphasis added). Converting a single use device into a reusable device **changes** that device’s intended use—and, as such, *statutorily* requires 510(k) clearance. *See* Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107–250, 116 Stat. 1588 (amending 21 U.S.C. § 321(d)(2)(A)). There has been no such legislative intervention for

¹³ While Intuitive seeks to exclude Prof. Elhauge’s opinions as to his *damages* estimates for those impacts, that motion is baseless. *See* Dkt. 164 (Opp. to Elhauge *Daubert* Mot.). Moreover, Intuitive has not sought to exclude Prof. Elhauge’s opinions as to the *fact* of these price and quality impacts (as well as other anticompetitive impacts). *See* Corrigan Dec. Ex. 1 § VI.A-C.

reusable devices, like an Endowrist, even though FDA has been deliberating the issue for decades. *See* Corrigan Dec. Ex. 84 ¶¶ 70–76.

Third, Plaintiffs are interested in EndoWrist repair. Franciscan’s head of medical equipment maintenance, for example, learned of Rebotix at a conference and, when Rebotix reached out to her, she circulated that email to others within Franciscan “to find out if there was any interest in evaluating that organization further . . . in the context of cost savings.” Spector Dec. Ex. 126 at 36:13–17. Franciscan did not move forward because of “language in [its] contracts with Intuitive Surgical that prevented [them] from taking any further action.” *Id.* at 36:23–37:2; *see also* Corrigan Dec. Ex. 52 at 93:16–95:13. Larkin considered using IRC Revanix to reset/repair its EndoWrists to save money on its robotic surgeries. Spector Dec. Ex. 134 at 14:10–15:4 (describing “conversations” with Revanix about “reset[ting] the counter on the instruments” and “lowering the cost of the surgery by extending the life of the instrument”). Larkin ultimately did not move forward with Revanix because it did not want Intuitive to cancel its da Vinci warranties. *Id.* at 25:6–26:15, 81:9–84:14. Valley Medical is “always looking at cost,” *Id.* Ex. 135 at 34:8–9, and, had it been aware of substantial cost savings offered by EndoWrist repair, *see* Corrigan Dec. Ex. 27 at 180:24–181:4; Spector Dec. Ex. 121 at 38:9–13, it would have been interested. *See also id.* Ex. 136 at 50:4–19 (VMC’s chief of surgery would be comfortable using repaired EndoWrists approved by VMC). That Valley Medical did not know of EndoWrist repair is simply a product of Intuitive’s comprehensive (and devastatingly effective) campaign to ward off competition in that market.

c. IRCs can (and would) repair X/Xi instruments.

Intuitive’s final argument seeks summary judgment only on Plaintiffs’ claims relating to X/Xi EndoWrists on the ground that “there has never been an entity in the marketplace with the *ability* to modify X/Xi EndoWrists to reset their use counters.” Mot. at 19. Intuitive is wrong. Rebotix’s Stan Hamilton testified that the company has developed the technical know-how to reset X/Xi EndoWrists. *See* Spector Dec. Ex. 119 at 39:14–40:22. When counsel for Intuitive asked, “has Rebotix taken an EndoWrist, an Xi EndoWrist . . . and add[ed] more lives to it,” Hamilton was unequivocal: “[Y]es, we have done that. . . . We know exactly how to do it from a technical

perspective.” *Id.* at 41:17–25. Had Intuitive not quelled any opportunity for EndoWrist repair, more IRCs likely would have made the necessary investment to develop similar capabilities, and earlier. *See* Corrigan Dec. Ex. 1 ¶¶ 163, 263–64, 275; *id.* Ex. 2 ¶ 416. Indeed, Restore was “a hundred percent” confident that it would be able to bypass the X/Xi chip, but had not invested in doing so because of Intuitive’s “blocking.” Spector Dec. Ex. 137 at 139:23–140:4, 141:14–21. And Stryker Corp.—a multi-billion-dollar medical technology company—considered entering this market, only to be discouraged by Intuitive’s anticipated retaliation to the venture. *See e.g., id.* Ex. 138 at 36:1–37:11, 46:23–47:11, 58:2–24. In the course of its due diligence, Stryker’s “R&D did not identify any technical showstoppers.” *Id.* Ex. 139 at -262.

Intuitive also ignores evidence that adding encryption to the X/Xi EndoWrist use counter was itself an anticompetitive design change.¹⁴ Intuitive admits that the chip included in its X/Xi EndoWrists was “encrypted for security purposes to avoid tampering.” Mot. at 5. And, during internal deliberations regarding “whether encryption [wa]s needed” for the RFID chip used in the X/Xi instruments, Intuitive officials were candid that “the most important thing is to prevent people from reprocessing our instruments.” Spector Dec. Ex. 115. The but-for world would not include this encryption, removing this barrier to IRC repair of X/Xi EndoWrists.

2. The record belies Intuitive’s purported procompetitive justifications.

Intuitive next claims that, even if Plaintiffs have suffered a cognizable antitrust injury, procompetitive reasons justify the use limits Intuitive imposed on EndoWrists and its associated crackdown on customers who used EndoWrist repair services. Mot. at 21–24 (Intuitive’s motion does not advance any justification for its robot servicing restrictions). A “procompetitive rationale is ‘a [1] nonpretextual claim that [the defendant’s] conduct is [2] indeed a form of competition on the

¹⁴ Contrary to Intuitive’s representations, Plaintiffs do expressly claim that this design change was part of Intuitive’s unlawful conduct. *See* Dkt. 52 (Consol. Am. Compl.) ¶¶ 143, 162, 196. And although Intuitive attempts to rely on the Ninth Circuit’s decision in *Allied Orthopedic* to argue that “the antitrust laws cannot be used to challenge product improvements,” Mot. at 19 n.10, this Court acknowledged that case when holding that an antitrust claim may lie where (as here) “[t]here is no technical or safety justification for Intuitive Surgical’s redesign of the use counter in its Xi generation EndoWrist instruments” and that “Intuitive Surgical redesigned the use counter for the sole purpose of preventing competition.” *SIS*, 571 F. Supp. 3d at 1141.

merits because it involves, for example, greater efficiency or enhanced consumer appeal.” *Epic Games, Inc. v. Apple, Inc.*, 2023 WL 3050076, at *20 (9th Cir. Apr. 24, 2023) (citation omitted). Claimed efficiencies “that have significant anticompetitive effects but only minimal procompetitive benefits” are properly rejected as “pretextual.” *Id.* at *26. Intuitive’s rationales are pretextual.

Intuitive argues that its use limits “were necessitated by concrete factual imperatives recognized as legitimate by the regulatory authority,” Mot. at 22–23 (quoting *Phonetele, Inc. v. AT&T Co.*, 664 F.2d 716, 737–38 (9th Cir. 1981)), and that its enforcement of those limits should be carried along for the ride. *Id.* at 24.¹⁵ As an initial matter, that argument notably is *not* a straightforward claim that Intuitive’s use limits and its policing of them are justified by safety concerns (which Intuitive presumably recognizes would be a losing summary judgment argument given the ample evidence of repaired EndoWrists’ safety). *See* Dkt. 149 (Pls.’ SJ Br.) at 7 (gathering evidence); *see also* Spector Dec. Ex. 116 ¶¶ 157–73. Rather, Intuitive attempts to lower its evidentiary burden, claiming only that “it had a ‘reasonable basis’ for concluding that EndoWrist use limits were needed” and that “FDA, as the governing authority, agreed.” Mot. at 23. But that argument fails twice—first, because FDA has never endorsed the use limits, nor Intuitive’s efforts to block IRCs from extending them, and second, because the record shows that profit, not safety, motivated Intuitive’s imposition of use limits and its enforcement of them.

¹⁵ Intuitive also accuses Plaintiffs of “regularly forget[ting] that they have no basis under the *antitrust* laws to challenge the use limits themselves.” Mot. at 22. That argument, however, mischaracterizes the nature of the challenged conduct and Plaintiffs’ antitrust injury. Plaintiffs challenge the use limits as part of a broader scheme by Intuitive to prevent *any* repair or extended use of EndoWrists. In addition to resetting the use counter, IRCs provided inspection, tune-up, and testing to allow safe and effective extended use of EndoWrists. Spector Dec. Ex. 116 ¶¶ 77-101. Intuitive’s restraints work together to prohibit and prevent *all* of these services (and other than the use limits, Intuitive does not even attempt to justify its restrictions). In the absence of this scheme, hospitals could repair used EndoWrists instead of buying new ones, thereby pressuring Intuitive to cut prices and eliminate or extend EndoWrists’ use limits. *See, e.g.*, Corrigan Dec. Ex. 1 ¶¶ 332-349. Notably, there are competitive options for service and repair of traditional laparoscopic instruments, *see, e.g., id.* ¶¶ 55–58, that exist without use limits. *See, e.g., id.* Ex. 7 ¶¶ 28-29. Intuitive is, as a result, simply wrong that “in a but-for world without use limits, competition would not be enhanced.” Mot. at 22.

There is no “safety” exemption from the antitrust laws,¹⁶ and, as described above, *see supra* Section III(A)(1)(a), whether Intuitive had a reasonable basis to conclude that use limits were necessary is at least a factual dispute. Even if Intuitive could show it believed it needed to impose use limits on EndoWrists in order to obtain FDA clearance to market them, it cannot possibly show that its self-appointed role as “510(k) police”—complete with threats to stop servicing hospitals’ robots and void their warranties if they used services from *some other entity*—was in any way compelled by regulatory authority.

To the contrary, Intuitive’s own foundational business plans clearly show that the use limits were conceptualized and implemented as a way to “control[]” and restrict the “number of reuses... *to reflect . . . the gross margin and price desired*” as part of the company’s plan to “derive its revenues from [these] high margin . . . instruments”—in other words, to artificially increase Intuitive’s profits, not promote safety or compliance with FDA requirements. Corrigan Dec. Ex. 9 at -675, -682 (emphasis added). Although Intuitive now argues that “the determination that use limits were needed” occurred “long before there was any suggestion that third parties” like Rebotix or Restore surfaced (Mot. at 23), Intuitive developed this business model nearly three decades ago, before “submit[ing] any designs to FDA” or holding even “preliminary meetings with the agency.” Corrigan Dec. Ex. 9 at -691. And Intuitive can point to no evidence that FDA required Intuitive to take any specific actions, including those challenged in this case, to enforce any use limitations—actions Intuitive obviously took only once faced with competition from IRCs.

Because Intuitive has failed to identify any nonpretextual procompetitive justifications, much less any that are legitimate beyond dispute of material fact, the Court need not reach the issue of

¹⁶ “In our complex economy the number of items that may cause serious harm is almost endless,” but “[t]he judiciary cannot indirectly protect the public against this harm by conferring monopoly privileges on the manufacturers.” *Nat’l Soc’y of Pro. Eng’rs v. U.S.*, 435 U.S. 679, 695–96 (1978); *see also FTC. v. Ind. Fed’n of Dentists*, 476 U.S. 447, 463–64 (1986) (finding anticompetitive conduct not justified by “noncompetitive ‘quality of care’ justifications”); *Wilk v. Am. Med. Ass’n*, 895 F.2d 352, 361 (7th Cir. 1990) (“It is not enough to carry the day to argue that competition should be eliminated in the name of public safety.” (citation omitted)); *Teladoc, Inc. v. Texas Med. Bd.*, 112 F. Supp. 3d 529, 540 (W.D. Tex. 2015) (rejecting the “notion that improved public safety was a sufficient justification” for anticompetitive policy restricting access to telemedicine).

whether Plaintiffs can demonstrate the existence of less restrictive alternatives. Mot. at 23–24.

Nonetheless, Plaintiffs have identified such alternatives to achieve any of Intuitive’s purported safety or regulatory justifications. Plaintiffs propose that Intuitive measure instrument usage based on “the period of time the instrument is in active use” or “the force with which it is applied during surgery.” Mot. at 24. Although Intuitive criticizes Plaintiffs for this alternative, the record is unambiguous that Intuitive “has the ability to monitor how long an EndoWrist was actually used during surgery as well as the types of forces and movements that the EndoWrist experienced during each surgery.” Spector Dec. Ex. 116 ¶ 230; *id.* Ex. 140 at 13:22–15:15; 16:6–17:14; 18:25–19:10. It is also undisputed that Intuitive already collects and shares information with surgeons concerning the duration of instrument use through the MyIntuitive App. *Id.* Ex. 141 at 145:16–146:1.¹⁷

Intuitive does not challenge Plaintiffs’ other proposed less restrictive alternative to use limits, which is simply to educate hospitals on how to evaluate the condition of used or repaired EndoWrists. *See, e.g.*, Corrigan Dec. Ex. 1 ¶¶ 383–84. This approach does not involve additional costs because Intuitive already provides hospitals with instructions and educational materials on using and handling (e.g., properly sterilizing) EndoWrists as a primary way of ensuring their safety and efficacy.¹⁸ *See, e.g.*, Spector Dec. Ex. 142; *id.* Ex. 120 at 54:12–18. Evidence indicates this would be as effective a method of achieving any safety or regulatory objectives since Intuitive’s use counter does not measure the actual condition of the instrument, *see, e.g.*, *id.* Ex. 116 ¶¶ 212–62; Corrigan Dec. Ex. 7 ¶¶ 12, 28–36, and hospitals are “highly sophisticated” consumers (as Intuitive puts it) with extremely strong incentives to ensure patient safety. Mot. at 5; Corrigan Dec. Ex. 1 ¶ 385; *id.* Ex. 3 ¶¶ 384–98. As to Intuitive’s “policing” activity, the obvious alternative is to leave any enforcement (or forbearance) to FDA.

In essence, Intuitive’s “justification” for its anticompetitive conduct is a paternalistic view

¹⁷ Intuitive’s motion to exclude Dr. Parnell’s testimony is meritless. *See* Dkt. 162 (Opp. to Parnell *Daubert* Mot.) at 9–10.

¹⁸ And in fact, Intuitive relies on surgeons to evaluate EndoWrist safety in the event of a failure. *See supra* Section II.

that it should be the sole arbiter and enforcer of its own regulatory interpretations. But hospitals and surgeons are more than capable of accounting for patient safety where anticompetitive repair restrictions do not exist, and a reasonable jury could find they would similarly do so here in the absence of Intuitive’s anticompetitive conduct. There is no reason to believe that they “lack incentives to consider the welfare of the patient as well as the minimization of costs” or to expect them “to sacrifice quality in return for cost savings.” *Ind. Fed’n of Dentists*, 476 U.S. at 463–64.

Ultimately, whether Intuitive’s conduct is justified is a matter that “must be developed at trial.”¹⁹ Given the factual disputes concerning Intuitive’s procompetitive justification defense, it cannot support summary judgment. *See Fox v. Good Samaritan Hosp.*, 2007 WL 2938175, at *10 (N.D. Cal. Oct. 9, 2007) (denying summary judgment despite “persuasive evidence” that a hospital privileges rule was “implemented for the improvement of patient care and did not have significant anticompetitive effects,” due to evidence that the rule “was targeted to preclude competition . . . that patient welfare suffered and that the reason given for the implementation of the rule was pretextual”); *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 479 (1992) (“We need not decide whether” defendant’s policy “has any procompetitive effects,” because “when we weigh the risk of deterring procompetitive behavior by proceeding to trial against the risk that illegal behavior will go unpunished, the balance tips against summary judgment”).

B. Intuitive is not entitled to summary judgment on Plaintiffs’ service claims.

Intuitive argues that Plaintiffs cannot establish that Intuitive’s service-related conduct caused antitrust injury because none of them sought to purchase da Vinci robot servicing from any IRC. Mot. at 20–21. That contention is irrelevant, as Plaintiffs can establish that they pay supracompetitive prices for service from Intuitive. If not for Intuitive’s servicing prohibitions, IRCs could have provided some level of service at discounted prices, causing Intuitive to compete on

¹⁹ *Phonetele*, 664 F.2d at 738. Much of the authority cited by Intuitive in Section III.C are decisions reached after trial. *See, e.g., NCAA v. Alston*, 141 S. Ct. 2141 (2021); *Ohio v. American Express Co.*, 138 S. Ct. 2274 (2018); *FTC v. Qualcomm Inc.*, 969 F.3d 974 (9th Cir. 2020); *Epic Games, Inc. v. Apple, Inc.*, 559 F. Supp. 3d 898 (N.D. Cal. 2021); and *Southern Pacific Communications Co. v. AT&T Co.*, 740 F.2d 980 (D.C. Cir. 1984).

price. Corrigan Dec. Ex. 1 ¶¶ 234, 365–66, 412–14. Professor Elhuage offers a reliable damages calculation showing significant overcharges for each named Plaintiff and the class. *Id.*, Table 8.²⁰

Plaintiffs were interested in IRC da Vinci servicing. Franciscan reduces costs by servicing complex medical equipment in-house or through IRCs, and requested the ability to do the same with its da Vincis, but Intuitive refused. *See* Spector Dec. Ex. 126 at 21:8-21, 60:12-15.²¹ Intuitive stressed to Valley Medical it risked “the cancelling of any warranties or cancelling of the service contract” if “somebody else does perform service.” *See id.* Ex. 143 at 37:22-38:7. This type of threat was not unique to Valley Medical; Intuitive successfully made similar threats to deter hospitals from even *inquiring* into IRC servicers. *See e.g., id.* Ex. 144 at 192:24-193:2; *id.* Ex. 145.

Finally, Intuitive’s argument that it made no economic sense for most customers to employ IRCs presents a contested question of material fact, and completely ignores the evidentiary record. First, Intuitive executives knew that customers were concerned with the high costs for service. *See id.* Ex. 146; *id.* Ex. 147 at -384. Further, Intuitive customers were searching for alternative da Vinci servicers. For example, one large hospital system executed a da Vinci service agreement with Restore in early 2019, at a potential savings of several hundred thousand dollars, despite Restore not being able to satisfy all its service needs. *See* Corrigan Dec. Ex. 50; *id.* Ex. 1 n. 281. An executive at another facility was [REDACTED]

[REDACTED] Spector Dec. Ex 148; *see also id.* Ex. 137 at 162:16-25. These facts are buttressed by Plaintiffs’ economic expert, who opined that the entire nationwide market for da Vinci service would have benefitted from the existence of IRC da Vinci servicers, regardless of their servicing preference. *See* Corrigan Dec. Ex. 1 ¶ 414. Intuitive’s characterization of this opinion as

²⁰ Plaintiffs note here the damages analysis of Intuitive’s economic expert, Dr. Loren Smith. While Dr. Smith includes a conclusory statement, supported by no calculations, that “no damages are warranted” (Corrigan Dec. Ex. 17 ¶ 236), he then spends the next 22 pages (*id.* ¶¶ 237-269) making various criticisms of Prof. Elhuage’s damages estimates, all supported by calculations, such that he finds damages for each of the 3 named plaintiffs [Valley Medical (\$74,174), Franciscan (\$951,313) and Larkin (\$195,437)], and just under \$420 million in class-wide damages. *See Id.*, Table 5.

²¹ Although Intuitive may argue that self-service does not count as competition, it is in fact a potential source of competition that the SLSA also prohibits. *See* Corrigan Dec. Ex. 1 ¶ 314.

“speculative” (Mot. at 21) is incorrect and cannot alter the factual nature of the question of whether it makes economic sense for hospitals to use IRCs to service their da Vincis.

Intuitive separately asserts there is no evidence that its conduct materially and adversely impacted competition (Mot. at 25), but that is untrue. The record provides ample evidence of demand for IRC da Vinci service, *See* Spector Dec. Ex. 148; *see also id.* Ex. 137 at 162:16-25, and of an IRC capable of servicing da Vincis, even without Intuitive’s proprietary toolkit. *See* Corrigan Dec. Ex. 50. Well-funded and experienced medical equipment service providers were interested in entering the da Vinci service market, due in part to the potentially high margins. *See* Spector Dec. Ex. 137 at 161:4-12; Corrigan Dec. Ex. 1 ¶¶ 317, 324. However, both service providers and their potential customers were stymied by Intuitive. *See* Spector Dec. Ex. 137 at 165:7-19; *id.* Ex. 143 at 38:1-7; *id.* Ex. 126 at 60:18-22. Further, the court in *Restore*, considering precisely the same question and similar evidence, held that a “jury could find that as a matter of ‘market reality,’ Intuitive effectively forces customers into using its da Vinci repair services (even those services that do not require the distributor’s toolkit)” and “that Restore could (and did) still perform some services on the da Vinci without access to that technology but for the impacts of the exclusive dealing provisions of” Intuitive’s agreements. *Restore*, 2022 WL 1495005, at *4.

IV. Plaintiffs are entitled to partial summary judgment as to Intuitive’s 510(k) defense, market definition and monopoly power

In their opening brief, Plaintiffs identified two narrow issues on which there is no genuine dispute of material fact: a) the impact (or lack thereof) of 510(k) clearance requirements on Plaintiffs’ ability to establish antitrust injury; and b) Intuitive’s monopoly power in the separate markets for Robots and EndoWrists. Intuitive’s opposition, *see* Mot. at 25–29, does not change the fact that (1) FDA has done nothing to stop IRCs from repairing and resetting EndoWrists without 510(k) clearance, and (2) even an actual, enforced 510(k) clearance requirement would not foreclose Plaintiffs from showing antitrust injury. *See supra* Section III(A)(1)(a).

Intuitive’s arguments with respect to market definition and monopoly power are similarly weak. Courts grant summary judgment as to market definition when the defendant fails to materially

rebut the plaintiff's evidence of a relevant market, even in the face of unexcluded opposing expert testimony that falls short of creating a genuine factual dispute.²² That is exactly the situation here, as Intuitive and its economic expert concede many facts supporting Plaintiffs' market definition and monopoly power arguments, and offer irrelevant rejoinders that fail to create any genuine disputes.

First, that EndoWrists are a separate product from da Vincis is clearly established by the robust demand for IRC EndoWrist repair as a standalone product, despite Intuitive's ban on such services. Dkt. 149 (Pls.' SJ Br.) at 10-11. It is undisputed that IRCs profitably sold EndoWrist repair to numerous customers, proving "sufficient consumer demand so that it is efficient for a firm to provide [EndoWrists] separately from [da Vincis]," which is all that is required. *Kodak*, 504 U.S. at 462.²³ Intuitive's citation to hypothetical testimony by hospital witnesses that *if* 510(k) clearance were required for EndoWrist repair, and *if* such service lacked FDA clearance, then those hospitals *might* not use them (Mot. at 26) does not create a *material* factual issue. Its argument further fails because (1) FDA has not taken such a position; (2) many hospitals (including two of the three Plaintiffs) demonstrated demand for such services without 510(k) clearance; and (3) 510(k) clearance can be and has been obtained for EndoWrist repair. *See supra* Sections III(1)(A)(a)-(b). Nor can Intuitive dispute that EndoWrists are bought separately from and not in a fixed ratio with the da Vinci, or that Intuitive treats the two as separate products. Dkt. 149 (Pls.' SJ Br.) at 11-12.²⁴

²² *See United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1166-76 (N.D. Cal. 2017); *In re Zetia (Ezetimibe) Antitrust Litig.*, 587 F. Supp. 3d 356, 360-66 (E.D. Va. 2022).

²³ Indeed, the "development of [an] entire high-technology service industry" for healthcare equipment "is evidence of the efficiency of a separate market for service"—here, EndoWrist repair that substitutes for new EndoWrists. *Kodak*, 504 U.S. at 462; FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices, at 1, 19 (May 2018), <https://www.fda.gov/media/113431/download> ("[T]he continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.").

²⁴ The SLSA language, oddly cited by Intuitive (Mot. at 6), only confirms Plaintiffs' point: "Instruments . . . will be made available . . . pursuant to separate orders placed . . . from time to time in accordance with the terms and conditions of the then current Instrument and Accessory Catalog." Cahoy Dec. Ex. 11 at -490 (emphasis added); *see also* Cahoy Dec. Ex. 12 at -318 (similar). This language is materially the same as language from contracts the Supreme Court has found to constitute tying. *See Int'l Salt Co. v. U.S.*, 332 U.S. 392, 395 n.6 (1947), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006).

See Jefferson Par. Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 22 (1984) (products separate where billed for separately and they “could be provided separately”), *abrogated by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006). Dr. Smith’s opinion that the da Vinci and EndoWrists are sold “as a single product” ignores these facts and is irrelevant, because the governing test “turns not on the functional relation between [the products], but rather on the character of the demand for [them],” and on whether “consumers, ‘when given a choice,’ opt to purchase the goods from different firms, rather than a single firm.”²⁵

Second, Plaintiffs present overwhelming proof that laparoscopic and open surgery tools are not economic substitutes for Robots, given Robots’ distinctive qualities and perceived advantages, surgeon and patient demand for minimally invasive robotic surgery (“MIRS”), Intuitive’s monopoly margins, and its repeated admissions about having no real competition (a view universally shared by other market participants). Dkt. 149 (Pls.’ SJ Br.) at 12–14; *see also Teikoku*, 296 F. Supp. 3d at 1169–76 (granting plaintiffs summary judgment based on evidence of lack of demand cross-elasticity, including defendant’s description of its product as “a unique product with unique advantages”); *Brown Shoe Co. v. U.S.*, 370 U.S. 294, 325 (1962) (explaining “practical indicia” of market definition). Instead of meaningfully disputing this evidence, Intuitive tries to confuse the issue by noting that MIRS, laparoscopy, and open surgery are to some extent functional substitutes, among which surgeons and patients may choose at the *individual procedure* level. Mot. at 28.²⁶ But

²⁵ *SIS*, 571 F. Supp. 3d at 1139 (first quoting *Jefferson Parish*, 466 U.S. at 19; and then quoting *Rick-Mik Enters., Inc. v. Equilon Enters. LLC*, 532 F.3d 963, 975 (9th Cir. 2008)) (emphasis added in second quote). That CMR may design its Robot for use with its own instruments does not help Intuitive. Bundling by *some* but not all firms (as exists here, *see* Dkt. 149 (Pls. SJ Br.) 10–12), indicates the products are separate. Corrigan Dec. Ex. 3 § II.B.1.iii. Dr. Smith’s opposite view lacks any basis in economic literature and is based solely on a misapplication of a treatise Prof. Elhauge himself wrote. *Id.* ¶¶ 168–69. And Intuitive offers no evidence that CMR bans IRC repair, which is the more relevant type of bundling at issue here. *Id.* ¶¶ 172–73. Further, CMR’s robot is not licensed to operate in the U.S. and it has sold a grand total of nine robots outside the U.S. *Id.* Ex. 17 ¶ 90.

²⁶ While Intuitive contends that its profit margins do not indicate monopoly power, it does not dispute those margins or that they are “high.” Mot. at 27–28. Moreover, Intuitive fails to substantiate its suggestion that these margins may be explained by fixed costs such as R&D. Dr. Smith provides no concrete evidence to rebut Prof. Elhauge’s showing that Intuitive’s margins are above competitive levels, and Intuitive’s R&D expenditures as a percentage of revenue are less than

“therapeutic substitutability cannot replace the showing of cross-price elasticity key to defining the relevant product market,” which “gauges ‘the substitutability of products *from the point of view of buyers.*’” *Zetia*, 587 F. Supp. 3d at 364-365 (quoting *Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 438 n.6 (3d Cir. 1997)); accord *Teikoku*, 296 F. Supp. 3d at 1167-72. Here, those buyers are not surgeons and patients, but hospitals and surgery centers, which have steadily increased their purchases of Robots over time as MIRS has inexorably gained traction over laparoscopic and open surgery for many procedures (despite their significantly higher costs), to the point of becoming “the standard of care” for some procedures, such that *all* of the nation’s top 100 hospitals offer da Vinci surgery. Dkt. 149 (Pls.’ SJ Br.) at 12–13; Corrigan Dec. Ex. 1 (Elhauge Rep.) ¶ 22. With zero percent of those hospitals substituting away from the da Vinci, it is clear that Robots occupy their own, distinct product market. *See id.* Ex. 3 § II.A (debunking Dr. Smith’s market-definition arguments). And Intuitive does not deny that it possesses monopoly power (with its 98-99% market share) if that is the case.

Finally, even setting aside its attempt to shoehorn EndoWrists into the Robot market, Intuitive effectively concedes that it also has monopoly power in the EndoWrist market. Mot. at 28–29. Intuitive disputes that *repaired* EndoWrists are part of that market, but not that the many customers who used repaired EndoWrists viewed them as equivalent to new EndoWrists, or that repaired EndoWrists competitively constrain new EndoWrist pricing. Dkt. 149 (Pls.’ SJ Br.) at 17–18. These undisputed facts establish that new and repaired EndoWrists are in the same market.

V. Conclusion

For these reasons, the Court should deny Intuitive’s motion for summary judgment and grant Plaintiffs’ motion for partial summary judgment.²⁷

relevant comparators. *See* Corrigan Dec. Ex. 1 ¶¶ 130–31, 188–89, 235–36; *id.* Ex. 3 ¶ 341; *id.* Ex. 17 ¶¶ 155–57, 166–72. Thus, the record indicates these margins are indeed supracompetitive, unlike in the cases Intuitive cites. Mot. at 27.

²⁷ Intuitive’s practices fall in the crosshairs of recent “right to repair” policymaking and litigation. *See, e.g.*, July 7, 2022 FTC article, <https://www.ftc.gov/business-guidance/blog/2022/07/ftc-announces-three-right-repair-cases-do-your-warranties-comply-law> (reporting on FTC right-to-repair settlements with 3 manufacturers).

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